K083724

SEP - 2 2009

Wiener lab.
Especialidades para Laboratorios Clínicos
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Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K083724 **"**

Introduction	According to the requirements of 21 CFR 862.1340, the following information provides sufficient details to understand the basis of a determination of substantial equivalence
1) Submitter Name, Address, Contact	Wiener Laboratorios S.A.I.C. Riobamba 2944 2000 – Rosario – Argentina Tel: 54 341 4329191 Fax: 54 341 4851986 Contact person: Viviana Cétola Date Prepared: 25th November 2008
2) Device name	Proprietary name: Wiener lab. Urine Strip Common name: Urinary glucose (non quantitative) test system Occult blood test Classification names: Regulatory Class I: JIN, JMT, CDM, JIR, JJB, LJX, CEN, JMA Regulatory Class II: JIL, JIO Device Class II

510(k) Summary, Continued

<table>
<tr><td>3) Predicate Device</td><td>We claim substantial equivalence to the currently marketed device Bayer Multistix® 10SG reagents strips</td></tr>
<tr><td>4) Device description</td><td>Wiener lab. Urine Strip are plastic strips to which glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leucocytes and ascorbic acid reagents pads are affixed.
The reagent pads react with the urine and provide a visible color reaction.
The product is packaged in a plastic bottle. Each strip is stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. The instructions for use must be followed exactly. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. Laboratory instrumentation is not required.</td></tr>
<tr><td>5) Intended use</td><td>Wiener lab. Urine Strip is intended for detection of glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leucocytes and ascorbic acid in urine.</td></tr>
<tr><td>6) Equivalencies and differences</td><td>The Wiener lab. Urine Strip test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Bayer Multistix® 10 SG.
The following table illustrates the similarities and differences between the Wiener lab. Urine Strip test system and the currently marketed Bayer Multistix® 10 SG.
<table>
<tr><th></th><th>BAYER Multistix® 10 SG</th><th>WIENER LAB. Urine Strip</th></tr>
<tr><td>Intended use</td><td colspan="2">For professional use</td></tr>
<tr><td>Intended Specimen</td><td colspan="2">Urine</td></tr>
<tr><td>Materials Provided</td><td colspan="2">Plastic strips affixed with several separate reagent areas</td></tr>
<tr><td>Working Temperature Range</td><td>15-30ºC</td><td>< 30ºC</td></tr>
<tr><td>Test Time</td><td>30 seconds - 2 minutes</td><td>60 seconds - 2 minutes</td></tr>
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	Glucose Methodology	Based on a sequential enzyme reaction. First, glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Then, peroxidase catalyzes the reaction of hydrogen peroxide with potassium iodide to colors ranging from greenish light-blue through greenish-brown and then to brown	
	Bilirubin Methodology	Based on the bilirubin and dichloroanilyne diazonium cupping and produces a strongly acid medium	Based on the coupling of bilirubin with 2,4-dichlorophenyl diazonium salt in a strong acid medium
	Ketone Methodology	Based on the reaction of acetoacetic acid in urine with nitroprusside	
	Specific Gravity Methodology	Based on the pKa change. In the presence of urinary cations, protons are released from a polyelectrolyte producing a color change	
	Blood Methodology	Based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3', 5,5' tetramethylbenzidine	Based on the pseudoperoxidase activity of hemoglobin, which catalyzes the reaction of 3,3',5,5'-tetramethylbencidine with buffered organic hydroperoxide
	pH Methodology	Based on double indicator principle that gives a broad range of colors covering the entire urinary pH range	
	Protein Methodology	Based on the color change of the indicator in the presence of proteins	
	Urobilinogen Methodology	Based on a modified Erlich reaction in which p-diethylaminobenzaldehyde in conjunction with a color enhacer reacts with urobilinogen in a strongly acidic medium	Based on the diazotization reaction of a diazonium salt and urinary urobilinogen in a strong acid medium
	Nitrite Methodology	Based on the reaction of urinary nitrite and p-arsenilic acid, forming a diazonium compound. This compound reacts with 1,2,3,4-tetrahydrobenzo(h)quinolin e-3-ol	Based on the reaction of the p-arsanilic acid and nitrite, derived from a dietary nitrate in the presence of bacteria in urine, to form a diazonium compound. This compound reacts with N-(1-naphthyl)-ethylenediamine in an acidic medium.

	Leucocytes Methodology	Granulocyte leucocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole that react with diazonium salt to produce a purple color	Based on the presence of granulocyte esterases. The esterases cleave a pyrazol ester derivative to release hydroxypyrazol derivative. This derivative reacts with diazonium salt to produce a purple product.
	Sensitivity	Proteins: 0.15-0.3 g/l (15-30 mg/dl)	
		Blood: 150-620 µg/l (0.015-0.062 mg/dl)	Blood: 0.015 mg/dl
		Nitrite: 0.06-0.1 mg/dl	Nitrite: 0.05-0.15 mg/dl
		Glucose: 75-125 mg/dl	Glucose: 100 mg/dl
		Ketones: 5-10 mg/dl acetoacetic acid	Ketones: 5 mg/dl acetoacetate
		Bilirubin: 0.4-0.8 mg/dl	Bilirubin: 0.5 mg/dl
7) Conclusion	Above mentioned data show substantial equivalency to the predicate device		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-G609
Silver Spring, MD 20993-0002

Wiener Laboratorios S.A.I.C.
c/o Dr. Viviana Cetola
Quality Control/Quality Assurance Manager
2944 Riobamba
Rosario, Santa Fe, Argentina 2000

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Re: k083724
Trade/Device Name: Urine Strip
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (non-quantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIO, CDM, JJB, JIN, JIR, JMT, LJX, CEN, JMA, JRE
Dated: July 17, 2009
Received: July 22, 2009

Dear Dr Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number: k083724

Device Name: Urine Strip

Indication for Use: Urine strip test strips are for "in vitro" diagnostic use and are intended for prescription use near-patient (point of care) and centralized laboratory locations.
Urine Strip includes test pads for qualitative and semi-quantitative determination of urobilinogen, glucose, ketones, bilirubin, proteins, nitrite, pH, blood, specific gravity, leukocytes and ascorbic acid in urine.
Urine test strips results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and urinary tract infections. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.
The test is to be read visually.

Prescription Use _x_ And/Or Over the Counter Use__(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off Office of In Vitro Diagnostic Device Evaluation and Safety

Carol Benson
Division Sign-Off

510(k) k083724

Office of In Vitro Diagnostic Device Evaluation and Safety

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